Notice of Allowability	Application No.	Applicant(s)	
	10/808,411	MORI ET AL.	
	Examiner	Art Unit	
	FRANK W. LU	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *RCE filed on 8/21/2009*.

2. ☒ The allowed claim(s) is/are *1-23 and 35-42*.

3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☒ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *10/28/2009* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Frank W Lu / Primary Examiner, Art Unit 1634	October 29, 2009

DETAILED ACTION

Reasons for Allowance

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Garth Dahlen (Reg. No. 43,575) on October 28, 2009.

2. The application has been amended as follows:

In the specification:

Replace "[F]igure 7 is an illustrative picture showing another embodiment of a check valve in a piston member" lines 12 and 13 of page 9 with --- Figures 7 (a) and 7 (b) are illustrative pictures showing another embodiment of a check valve in a piston member.

Deleting last sentence "[T]he use of the apparatus for separating and purifying nucleic acids of the present invention allows efficient separation of highly pure nucleic acids from a sample solution containing nucleic acids in a shorter time than before" in the abstract.

In the claims:

Combining claims 16-18 with claims 1-15, 19-23, and 35-42.

1. (Currently Amended) An apparatus for separating and purifying nucleic acids[, which comprises] comprising:

a cylindrical syringe having a leading end part in which a first opening part comprising an opening is formed, a base end part in which a second opening part comprising an opening is

formed and an accommodation part between said first opening part and said second opening part, the accommodation part being able to hold a sample solution therein;

a solid phase-holding member comprising a column with a circular shape, wherein the column comprises a top portion, a middle portion, and a bottom portion having a flow hole, and connects [connected] to said leading end part of said cylindrical syringe by the top portion of the column such that a part of the first opening part of the syringe is inside the column [a flow hole being formed at the leading end side of the solid phase-holding member];

a solid phase comprising an organic polymer having a hydroxyl group on the surface thereof, wherein the solid phase is accommodated in said solid phase-holding member, located only at the interior of the bottom portion of the column of [within] the solid phase-holding member and [at an] contacts with the opening of the first opening part of the leading end part of the cylindrical syringe at the interior of the column, and adsorbs and desorbs nucleic acids in the sample solution;

a pressure difference-generating apparatus, and

a pressure sensor capable of detecting the pressure in the accommodation part being connected to an operation part of the pressure difference-generating apparatus which couples to [an] the opening of the second opening part.

2. (Currently Amended) The apparatus for separating and purifying nucleic acids according to claim 37[, which] further comprises a liquid-tight member [provided] located at the leading end of said plunger, wherein the liquid-tight member can be brought into close contact with the inner surface of said accommodation part and is slidable in said accommodation part.

3. (Currently Amended) The apparatus for separating and purifying nucleic acids according to claim 37, wherein said piston member [is] further [provided with] comprises a check valve that is closed when said piston member is moved to the leading end part [side] of the syringe and that is open when said piston member is moved to the base end part [side] of the syringe.

4. (Currently Amended) The apparatus for separating and purifying nucleic acids according to claim 1, wherein the pressure difference-generating apparatus is a pump that is capable of putting the inside of the accommodation part of the syringe into a pressurized state.

5. (Currently Amended) The apparatus for separating and purifying nucleic acids according to claim 1, wherein a circular solid phase-supporting surface is formed on the inner surface of the [leading end side] bottom portion of the column of said solid phase-holding member, the solid phase-supporting surface being generally perpendicular to the longitudinal axis of said syringe; said solid phase [that] is formed in a circular shape and is placed in a direction parallel to said solid phase-supporting surface; the leading end of the leading end part of said syringe [that] is formed in a circular shape and is abutted to the immediate inside of the circular peripheral edge of said solid phase to press the solid phase to the side of said solid phase-supporting surface.

8. (Currently Amended) The apparatus for separating and purifying nucleic acids according to claim 6, wherein the surface saponification rate of the surface saponification product of acetyl cellulose is 5% or more.

9. (Currently Amended) The apparatus for separating and purifying nucleic acids according to claim 6, wherein the surface saponification rate of the surface saponification product of acetyl cellulose is 10% or more.

11. (Currently Amended) [An apparatus] A device for separating and purifying nucleic acids [which comprises] comprising a combination of at least two or more apparatuses for separating and purifying nucleic acids, wherein each [apparatus] of said apparatuses comprises a pressure sensor, and the pressure in the accommodation part of each of said apparatuses [apparatus for separating and purifying nucleic acids] can be independently detected,

wherein each of said [two or more] apparatuses is an apparatus for separating and purifying nucleic acids, which comprises:

a cylindrical syringe having a leading end part in which a first opening part comprising an opening is formed, a base end part in which a second opening part comprising an opening is formed and an accommodation part between said first opening part and said second opening part, the accommodation part being able to hold a sample solution therein;

a solid phase-holding member comprising a column with a circular shape, wherein the column comprises a top portion, a middle portion, and a bottom portion having a flow hole, and connects [connected] to said leading end part of said cylindrical syringe by the top portion of the column such that a part of the first opening part of the syringe is inside the column [a flow hole being formed at the leading end side of the solid phase-holding member];

a solid phase comprising an organic polymer having a hydroxyl group on the surface thereof, wherein the solid phase is accommodated in said solid phase-holding member, located only at the interior of the bottom portion of the column of [within] the solid phase-holding member and [at an] contacts with the opening of the first opening part of the leading end part of the cylindrical syringe at the interior of the column, and adsorbs and desorbs nucleic acids in the sample solution; and

a pressure difference-generating apparatus,

wherein the pressure sensor capable of detecting the pressure in the accommodation part is connected to an operation part of the pressure difference-generating apparatus which couples to [an] the opening of the second opening part.

12. (Currently Amended) A method for separating and purifying nucleic acids [which comprises] comprising adsorbing and desorbing the nucleic acids in a sample solution on a solid phase [comprised of] having an organic polymer having a hydroxyl group on the surface thereof and separating and purifying the nucleic acids by using the apparatus [for separating and purifying nucleic acids according to] of claim 1.

15. (Currently Amended) The method for separating and purifying nucleic acids according to claim 14, wherein the nucleic acid-solubilizing reagent is a guanidine salt[,] or a surfactant [and] or a protease.

16. (Currently Amended) The method for separating and purifying nucleic acids according to claim 12[, which comprises the steps of: adsorbing nucleic acids on a solid phase comprised of an organic polymer having a hydroxyl group on the surface thereof;] further comprising washing the solid phase using a nucleic acid washing buffer[;] and said desorbing comprising desorbing the nucleic acids adsorbed on the solid phase using a liquid capable of desorbing the nucleic acids adsorbed on the solid phase.

17. (Currently Amended) The method for separating and purifying nucleic acids according to claim 16, wherein the nucleic acid washing buffer is a solution containing methanol[,] or ethanol [,] or isopropanol[,] or n-propanol or mixture thereof in a concentration of 20 to 100% based on percentage by weight.

19. (Currently Amended) The method for separating and purifying nucleic acids according to claim 12, [which comprises] wherein said adsorbing and desorbing the nucleic acids further comprising the steps of:

(a) preparing [a] the sample solution containing the nucleic acids [by using] from a specimen, and charging said sample solution containing the nucleic acids from the opening of the second opening part of the syringe into said accommodation part of the syringe;

(b) pressurizing the inside of said accommodation part of the [apparatus for separating and purifying nucleic acids to discharge] the syringe and discharging the charged sample solution containing the nucleic acids from the [flow hole] opening of the first opening part of the syringe to bring the charged sample solution into contact with the solid phase [comprised of] comprising an organic polymer having a hydroxyl group on the surface thereof;

(c) charging a nucleic acid washing buffer from the opening of said second opening part of the syringe [apparatus for separating and purifying nucleic acids];

(d) pressurizing the inside of said accommodation part of the [apparatus for separating and purifying nucleic acids to discharge] the syringe and discharging the charged nucleic acid washing buffer from said [flow hole] opening of the first opening part of the syringe to bring the charged nucleic acid washing buffer into contact with the solid phase [comprised of] comprising an organic polymer having a hydroxyl group on the surface thereof;

(e) charging a liquid capable of desorbing the nucleic acids adsorbed on the solid phase [comprised of] comprising an organic polymer having a hydroxyl group on the surface thereof from the opening of said second opening part of the syringe [apparatus for separating and purifying nucleic acids]; and

(f) pressurizing the inside of said accommodation part of the [apparatus for separating and purifying nucleic acids to discharge] syringe, discharging the charged liquid capable of desorbing the nucleic acids from said [flow hole to desorb] opening of the first opening part of the syringe, desorbing the nucleic acids adsorbed on the solid phase [comprised of] comprising an organic polymer having a hydroxyl group on the surface thereof and discharge the nucleic acids to the outside of the apparatus for separating and purifying nucleic acids.

20. (Currently Amended) The method for separating and purifying nucleic acids according to claim 19, wherein in steps (b), (d) and (f), the pressure sensor capable of detecting the pressure in the accommodation part of the syringe is used to monitor the pressure in the accommodation part to sense the discharge of the charged sample solution in step (b)[,] or the charged nucleic acid washing buffer in step (d) or the charged liquid capable of desorbing nucleic acids in step (f) in the accommodation part by a pressure change, and wherein steps (c) and (e) start after sensing the discharge of the charged sample solution in step (b) or the charged nucleic acid washing buffer in step (d).

21. (Currently Amended) The method for separating and purifying nucleic acids[,] according to claim 19, wherein the pressurizing of the inside of said accommodation part in step (b) is stopped when the pressure [as] detected by the pressure sensor reaches a certain level.

22. (Currently Amended) The method for separating and purifying nucleic acids according to claim 19, wherein the pressurization in step (d) and/or step (f) are/is stopped when the pressure [as] detected by the pressure sensor reaches a certain level.

23. (Currently Amended) The method for separating and purifying nucleic acids according to claim 21, wherein when a certain pressure is set inside the accommodation part, [so that] no sample solution remains inside the accommodation part.

36. (Currently Amended) The method for separating and purifying nucleic acids according to claim 22, wherein the pressure sensor is used to detect [that] whether the pressure in the accommodation part has reached a certain level.

37. (Currently Amended) The apparatus for separating and purifying nucleic acids according to claim 1, wherein the pressure difference-generating apparatus is a piston member comprising a plunger extending from said second opening part [side] into said accommodation part [in a state] when the plunger is plunged into the inside of the accommodation part.

38. (Currently Amended) The apparatus for separating and purifying nucleic acids according to claim 1, wherein when said pressure sensor detects a certain preset pressure inside the accommodation part, it sends a signal for stopping the pressurization to the pressure difference generating apparatus, and thereby the pressurization [in the container can be] inside the accommodation part is stopped.

39. (Currently Amended) The apparatus for separating and purifying nucleic acids according to claim 11, wherein the pressure difference-generating apparatus is a piston member comprising a plunger extending from said second opening part [side] into said accommodation part [in a state] when the plunger is plunged into the inside of the accommodation part.

40. (Currently Amended) The apparatus for separating and purifying nucleic acids according to claim 39[, which] further comprises a liquid-tight member [provided] located at the leading

end of said plunger, wherein the liquid-tight member can be brought into close contact with the inner surface of said accommodation part and is slidable in said accommodation part.

41. (Currently Amended) The apparatus for separating and purifying nucleic acids according to claim 39, wherein said piston member [is] further [provided with] comprises a check valve that is closed when said piston member is moved to the leading end part [side] of the syringe and that is open when said piston member is moved to the base end part [side] of the syringe.

42. (Currently Amended) The apparatus for separating and purifying nucleic acids according to claim 11, wherein when said pressure sensor detects a certain preset pressure inside the accommodation part, it sends a signal for stopping the pressurization to the pressure difference generating apparatus, and thereby the pressurization [in the container can be] inside the accommodation part is stopped.

3. The following is an examiner's statement of reasons for allowance:

Claims 1-23 and 35-42 are allowable in light of applicant's amendments filed on June 24, 2009 and the examiner's amendments. The rejections under 35 U.S.C. 112, first and second paragraphs have been withdrawn in view of applicant's amendments filed on June 24, 2009 and the examiner's amendments. The claims 1 and 11 in the examiner's amendments are supported by Figures 1 and 3. The closest prior arts in the record are Huse *et al.,* (US Patent No. 5,378,360, published on January 3, 1995), Bach *et al.,* (US Patent No. 4,133,804, published on January 9, 1979) and Kojima *et al.,* (US Patent No. 6,179,569 B1, published on January 30, 2001). These prior arts do not teach or suggest that the solid phase is located only at the interior of the bottom portion of the column of the solid phase-holding member and contacts with the opening of the first opening part of the leading end part of the cylindrical syringe at the interior

of the column as recited in claims 1 and 11. These prior arts in the record do not teach or reasonably suggest an apparatus for separating and purifying nucleic acids and a device for separating and purifying nucleic acids which comprise all limitations recited in claims 1 and 11.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance".

4. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen, can be reached on (571)272-0731.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Frank W Lu /
Primary Examiner, Art Unit 1634
October 29, 2009